Historically, cancer care has been protected from many of the insurance issues that have beset other diseases. The life threatening nature of cancer was recognized by physicians, patients, and payers alike, and the barriers to obtaining payments from insurers were minimal. Over the past decade, however, this situation has changed. Policies dictated by insurers have begun to erode the protection that formerly characterized coverage of cancer treatment. This trend is manifested by reduced patient access to high quality cancer care and a lack of transparency regarding the recommended treatments.

As physicians, we are committed to providing the best care possible for our patients. However, we face serious challenges in meeting this goal, including the complex nature of cancer, involvement of multiple medical specialists, numerous treatment options, a confusing insurance system, and the inability of our patients to pay their sometimes outrageously high out-of-pocket expenses. Although it is not possible to instantly solve all of these problems, improvements in the areas of patient access and transparency are essential, and thus these are good places to begin.

IMPROVING PATIENT ACCESS TO CANCER TREATMENTS

The cost of cancer care in the United States exceeds $125 billion annually and is expected to increase nearly 40% by 2020.1 The escalating costs of treatment have been attributed to the aging population, increased diagnosis of cancer, and new state-of-the-art medications targeted at specific molecules on cancer cells.1 Many of these new medications dramatically improve the treatment of cancer and it is often argued that solutions to the cost issues must also preserve the development of innovative therapies.

In response to the demographic and economic trends in cancer care, insurers have devised a number of strategies designed to mitigate their costs. Unfortunately, many of these policies limit patient access to treatments from which they could benefit. Three of the main policies that must be amended in order for patients to access cancer therapies are (1) specialty tiers/high co-pays, (2) prior authorizations, and (3) parity of coverage not only for infusion and oral therapies, but also for site of care. Each of these policies is discussed in the following sections.
Specialty Tiers
Insurance plans typically incorporate several “tiers” that determine the level of patient cost sharing or the amount of medication cost that must be paid by beneficiaries (i.e., co-pay). The lowest level of cost sharing, tier 1, usually includes generic drugs. Tier 2, the next higher co-pay level, typically includes preferred name-brand drugs, and tier 3 includes non-preferred, name-brand drugs. Tier 4, or the “specialty tier,” includes the more expensive drugs such as those targeted toward specific types of cancer.

<table>
<thead>
<tr>
<th>Tier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>Generic drugs</td>
</tr>
<tr>
<td>Tier 2</td>
<td>Preferred name brand drugs</td>
</tr>
<tr>
<td>Tier 3</td>
<td>Non-preferred name brand drugs</td>
</tr>
<tr>
<td>Specialty Tier</td>
<td>Higher cost medications, including many cancer therapies</td>
</tr>
</tbody>
</table>

The problem with this scheme is that co-insurance costs for the specialty tier drugs are typically so high that many of our patients cannot afford them—or cannot do so without a significant financial hardship. For example, specialty tier medications cost $40,500-95,000 per patient per year⁴, and co-pays for drugs on the specialty tier often range from 25% to 33%.⁵ This means that patients who require a specialty tier drug with an annual cost of $60,000 would need to pay $15,000 out of pocket per year for their medication alone (based on a typical 25% co-pay) in addition to their other co-pays and deductibles for office visits, surgery, and hospital care. This is an exorbitant amount of money for most people. Further complicating this scenario is the impact of cancer on a person’s ability to work. Cancer and its treatment can lead patients to quit or lose their jobs and hence their insurance.

“I worry about the middle class. They make too much money to qualify for pharmaceutical company-sponsored assistance programs, but cannot afford the cancer medications. One of my patients was a professional whose cancer was not improving with treatment. I just couldn’t figure out why. After we lost him, I found out that he had not taken his high-cost medicine because he didn’t want to bankrupt his family. It goes without saying that such tragedies should not have to happen.”

-Dr. Nadim Nimeh, MD
which in turn can lead to insurmountable financial burdens, including bankruptcy. To help minimize the financial burden, many patients do not take their medications as prescribed, which of course reduces or even negates the effectiveness of treatment.

Hundreds of advocacy groups have alleged that the high patient costs for specially tier medications discriminate against those with cancer, multiple sclerosis, AIDS, and other chronic diseases—the ones who require specialty tier medications. Under many insurance plans, these patients are required to pay percentages rather than flat co-pays and higher overall dollar amounts for their medications than patients with other diseases. This is true even for insurance plans sold through exchanges developed under the Affordable Care Act, in which non-discrimination was a major provision.

Clearly, specialty tiers that require high co-pays are unaffordable for most patients. One potential solution is for insurers to raise their co-pays on lower-tier (i.e., less expensive) drugs to offset the costs of specialty tier medications. Other solutions are also possible, and it is imperative that stakeholders work together to identify policies that preserve the needs of insurers while increasing patient access to specialty tier cancer therapies.

**Prior Authorization**

Another policy that limits patient access to cancer treatments is prior authorization. Prior authorization is the approval of a therapy by insurers before it is given to a patient. The concept of pre-approval is not, in itself, a problem. However, problems arise when insurers take a prolonged time to approve therapies, particularly when they are urgently needed to help reduce cancer growth or, in the case of supportive care drugs such as hematopoietic growth factors, reduce the risk of serious complications of treatment. Some states have passed legislation that requires insurers to respond to prior authorization requests within 48 hours or the request is automatically approved. Moreover, due to variation in the forms physicians must fill out for pre-approval, the legislation requires that all prior authorization requests be standardized, with electronic submissions allowed. These steps greatly improve the prior authorization system and should be implemented by all states.

Prior authorization policies could be further improved with several additional common sense amendments. First, if...
insurers pre-authorize therapies, they should pay for them. Pre-authorized claims should not be up for re-review after they have been approved and the patient has already received the therapy. Although this seems intuitive, it is not uncommon for insurers to deny pre-authorized claims after the fact. Moreover, if the drug is being used in line with its Prescribing Information as approved by the US Food and Drug Administration, physicians should be able to treat patients prior to receiving pre-approval.

**Coverage Parity**

*Parity for Site of Service*

Coverage parity refers to comparable insurance coverage for comparable services and medicines. Several parity issues are at the forefront of cancer care today, one of the most notable of which involves the site of cancer care. In the United States, cancer treatment is available at various locations, including community clinics, hospitals affiliated with universities, and private hospital outpatient centers.

Although it seems logical for insurers to provide comparable coverage for medicines and services at all of these locations, certain treatment sites tend to have a disproportionate number of uninsured or underinsured patients—often in populous inner city areas. In order to make it possible for physicians and institutions to treat these patients, federal programs such as 340B Drug Pricing Program were implemented. The 340B program mandates that drug manufacturers sell medicines to qualifying institutions at significantly reduced prices. The goal of this program was to increase patient access by making needed medications available to more patients. There is general agreement that this program is very effective when applied as intended.

If this program were misused by eligible institutions, however, it could have an unforeseen consequence of contributing to the closure of local community cancer centers. These closures may prove problematic in rural areas where patients may have to drive many miles for care. Commuting to the city is difficult for patients with limited income and for seniors, who may have trouble navigating urban roadways and parking lots or must rely on family members or friends to drive them. Furthermore, seniors may feel more comfortable at local centers and may therefore be better able to explain their symptoms, which in turn will result in better care. Experts agree that local cancer centers are in danger of extinction, with a study by the American Society of Clinical Oncology (ASCO) finding that 63% of small oncology practices were likely to merge, sell, or close operations in the coming year.

*Infused Versus Oral Medications*

Another notable parity issue in cancer is the preference that insurers give to medications (i.e., chemotherapies) that must be injected or infused over those taken orally in the form of pills. Oral agents have a number of advantages over injection and infusion therapies, such as being more convenient—swallowing a pill is easier than traveling to a treatment center for a prolonged intravenous infusion and minimizes disruptions in work and everyday life. Moreover, many of the recently approved,
state-of-the-art medications that target molecules associated with cancer cells are available only in oral formulations. However, traditional infusion therapies are preferred for some patients due to personal and cancer-specific considerations.

In many states, insurers still differ in the extent to which they cover infusion therapies and oral therapies for the same types of cancer. For traditional chemotherapy administered via infusion into the vein, patients must typically pay a set fee for the medication and its infusion. Annual out-of-pocket costs are usually capped as part of the medical benefit of the patient's insurance plan. In contrast, oral agents to treat cancer are typically covered under patients' pharmacy benefit plan, which requires them to pay a percentage of the drug's cost—which can run into the tens of thousands of dollars annually if the drug is classified by the pharmacy benefit plan as "specialty tier." Moreover, there is often no out-of-pocket limit for these medications.

The good news is that 33 states and the District of Columbia have now passed laws requiring insurers to provide coverage parity for oral cancer therapies. Extending these laws to the remaining states is a priority for improving patient access to cancer care.

IMPROVING TRANSPARENCY IN CANCER CARE

Transparency of Costs, Coverage, and Co-Pays

Cancer patients are frequently surprised by the costs of care, the items covered or not covered by their insurance, and the out-of-pocket expenses for which they are responsible. Insurance-related costs are typically hidden in verbose policies that are difficult for patients to understand, and cancer centers studiously avoid publicizing the costs of their services and procedures. However, patients want to know these costs and to discuss them with their healthcare providers, as indicated by a recent survey of men with advanced prostate cancer.

“Reducing price variation for the 108 million Americans with employer sponsored insurance could save the nation as much as $36 billion per year.”
Thomson Reuters, 2012

In addition to the high costs of cancer care, several other developments are nudging the system toward greater transparency. These include patient access to electronic information and studies showing that healthcare costs for the same procedure in the same geographic area can vary by more than 100%. Indeed, it has been estimated that reducing price variation for insured individuals could save the US $36 billion annually.

To improve transparency, insurance plans should include clear formulary lists and provider networks. They should include the tiers and co-pays with real-world examples of amounts that patients would need to pay for some of the most common diseases. The costs of
therapies, including diagnostics, imaging, and medications, along with other fees, should be made apparent to patients.

**Transparency of Clinical Pathways**

Clinical pathways specify which treatments patients should receive and in which order. They are typically developed by physicians working with insurers who consider both available evidence and cost; in this way, clinical pathways can help reduce costs and even improve cancer care. Many clinical pathways are well designed and accepted by physicians. Unfortunately, however, some do not rely as heavily on evidence and are designed based on cost of care instead of professional consensus. The American Society of Clinical Oncology has outlined guiding principles for the development and use of cancer care pathways, as listed in the following table.

<table>
<thead>
<tr>
<th><strong>ASCO Guiding Principles for the Development and Use of Oncology Care Pathways</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pathways should be developed with the input of oncologists.</td>
</tr>
<tr>
<td>• Pathways should describe all aspects of cancer care, not just anti-cancer treatment.</td>
</tr>
<tr>
<td>• Pathways should give appropriate consideration to costs of alternative approaches to care.</td>
</tr>
<tr>
<td>• Oncology practices should be able to use the same pathways with all payers.</td>
</tr>
<tr>
<td>• Efficient methods of using pathways and of documenting and auditing adherence to pathways should be developed.</td>
</tr>
<tr>
<td>• 100% adherence to pathways is likely impossible and undesirable; deviations should be used to advance knowledge about appropriate care.</td>
</tr>
<tr>
<td>• Standards for adherence to pathways should be established in advance based on evidence and experience.</td>
</tr>
</tbody>
</table>

Following the development of clinical cancer pathways, insurers typically offer financial incentives to physicians or physician practices for adhering to them a certain percentage of the time. According to the US Oncology Network, this percentage is ideally about 80%—meaning that about 80% of patients are suitable for the pathways. This leaves room for flexibility 20% of the time to accommodate patients with special circumstances. For instance, if the clinical pathway specifies a treatment that can cause severe skin reactions, patients with a history of such reactions may be better suited to a different medication that provides comparable benefits but with less risk of skin reactions.

Perhaps more disconcerting are the insurers who pay physicians for each patient they keep on their pathways. For example, WellPoint, the second largest insurer in the US, pays oncologists $350 per patient per month to remain on one of their clinical pathways. In this case, there is a financial incentive for physicians to place each individual patient on a...
pathway. If physicians deviate from the pathway, which will certainly occur in selected cases, they will still get reimbursed. However, the physician will not receive $350 per month for those patients.

Moreover, clinical pathways can be different for each insurer, forcing physicians into a “treatment by insurance” routine where the treatment patients receive varies by which insurance they have. Many experts believe that it should be the practice or hospital that develops the pathways and insurance companies that agree to abide by them rather than the other way around.

Regardless of which clinical pathway is followed, however, patients have a right to know what care is being recommended for them and what they are scheduled to receive—that is, the pathway and the financial incentives must be transparent. Although many might decry the inability of patients to understand such information, there is clearly a trend toward greater patient engagement in cancer care and a call from the Institute of Medicine to provide information that patients can understand.

CONCLUSIONS
The cost of cancer care continues to rise, compromising our patients’ ability to access needed therapies. In an attempt to rein in their own costs, insurers may require exorbitant co-pays/co-insurance for state-of-the-art medications, fail to respond to requests for prior authorization in a timely manner, and, unbeknownst to the patient, pay doctors to place them on a clinical pathway designed to utilize treatments that combine efficacy with lower cost.

Part of the solution to the cost challenges may lie in greater transparency across the entire healthcare system. When costs of procedures and medications are readily accessible and insurance policies written in an approachable manner, patients will engage in informed healthcare choices.

These issues are especially critical in cancer given the serious nature of the disease. It is unfair for people who have paid their insurance premiums and/or Medicare payroll taxes for decades to be surprised by lack of adequate coverage when they need help paying for a life-and-death illness. Policymakers and citizens must work to protect patient access to cancer therapies by promoting transparency and rectifying patient unfriendly insurance practices such as specialty tiers, prolonged prior authorizations, and lack of equal coverage for comparable services and treatments.

Robert Miller, M.D.  Rachel Brem, M.D.  Lucy Langer, M.D.  David Charles, M.D.
Alan Marks, M.D.  Emily Chan, M.D.  Nadim Nimeh, M.D.

Please note that the views expressed in this document do not necessarily reflect those of the institutions with which the Working Group Members are affiliated.
References


This white paper is authored by the members of the Oncology Therapy Access Physicians Working Group and sponsored by the Institute for Patient Access.